



COMMONWEALTH of VIRGINIA

Department of Health 3 12 3 '99 APR -5 AMO :58

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March 29, 1999

Dockets Management Branch (HFA-305)
US Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Subject: Performance Standard for *Vibrio vulnificus*; Request for Comments

Dear Sirs,

We are responding to your request for comments concerning a petition by the Center for Science in the Public Interest (CSPI) to the U.S. Food and Drug Administration (FDA). This petition would establish a performance standard of nondetectable for the marine bacterium *Vibrio vulnificus* in molluscan shellfish intended for raw consumption and harvested from waters that have been linked to a case of shellfish-borne illness from this organism.

We have two types of comments that we wish to make. One concerns CSPI's assertion that Virginia shellfish from Virginia waters may be responsible for a case of shellfish-borne *V. vulnificus* infection and subsequent death. Secondly, we wish to comment upon the petition itself.

Incorrect assertion of a case of *Vibrio vulnificus* due to Virginia-raised shellfish

CSPI alleges in its petition (pgs. 8-9) that a death due to *Vibrio vulnificus* in shellfish harvested from or wet stored in Virginia waters may have occurred. This allegation is incorrect and without basis. The Virginia Department of Health and FDA performed a thorough investigation and the results indicated that this death was caused by oysters harvested in Virginia. The following is a summary of the events involving the death cited in the CSPI petition:

On **8/28/94** Dr. Yoshio Nakanishi ate raw oysters at The Fish Market Restaurant, Palo Alto, CA. He was hospitalized at Stanford Medical Center in serious condition on 8/31/94. He had contracted *Vibrio vulnificus*, developed septicemia and died on 9/13/94. Oysters from Stingray Point Oyster Co., Irvington, Virginia, were implicated.

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The oysters (180 sacks) were harvested by Hugo Osoraio on 8/22/94 from lease bed number 807 in Galveston Bay, Texas. Misho's Seafood Inc., San Leon, Texas, shipped the refrigerated oysters by a common carrier, Smithfield Truck Exchange. The shipment arrived at Stingray Point Oyster Co. on 8/24/94.

Ocean's Best, Kilmarnock, Virginia, the broker for Stingray Oyster Co., sold these oysters to Farrallon Fisheries in South San Francisco, and appears to have represented them as being harvested in Virginia. The 6,000 oysters were repacked and mislabeled by Stingray Point Oyster Co. as being Blue Point oysters, with a harvest date of 8/23/94 and a harvest location of Black Bay (Virginia does not have such a harvest area). The shellfish tags for this repacked product did not contain a state identification or original shipper's certification number. The oysters were flown to SFO airport on 8/25/94 via United Airlines flight #185. The 6,000 oysters were distributed by Farrallon Fisheries to The Fish Market chain restaurants on 8/27/94, 8/29/94, 8/30/94, 8/31/94 and 9/1/94.

CSPI states in their petition that "...some of the states listed above may have only suspected links to *Vibrio vulnificus* deaths and illness. Those states' regulators and producers should bear the burden of showing the cases tentatively traced to their state's waters were actually attributable to shellfish harvested elsewhere, and that those states should not be subject to the performance standard." There has not been a *Vibrio vulnificus* associated death or illness from molluscan shellfish harvested from or wet stored in Virginia waters. Therefore, if FDA decides to adopt a case-based performance standard for *Vibrio vulnificus*, Virginia should be **exempt** from this requirement.

CSPI's petition for a performance standard for *Vibrio vulnificus*

We will now address CSPI's petition to FDA for a performance standard for *V. vulnificus* in molluscan shellfish intended for raw consumption. We have some serious concerns about the lack of information available on many subjects germane to reaching a decision on the merits of such a performance standard. Before we would make such a decision, we would need answers to many questions. Some of the most pressing questions follow:

1. How reliable is the AmeriPure Process and has it been independently tested?
2. If the AmeriPure Process turns out not to be reliable, what other procedure is available for reducing the amount of either *V. vulnificus* or *V. parahaemolyticus* in shellstock shellfish? To our knowledge, freezing may be inconsistent in its killing

of *V. vulnificus*, irradiation has not been approved, and hydrostatic pressure is only in the experimental stages of development.

3. What is the potential for the outgrowth of *Clostridium botulinum* spores if the pasteurized shellfish are later temperature abused, and which potential problem (*i.e.*, intoxication or infection) is more significant?

4. How significant is the potential for a local black market for unprocessed shellstock to spring forth?

Most shellfish dealers are small operations and could not afford to purchase expensive processing equipment. While dealers could theoretically ship their shellstock to a processing center, this would add a significant degree of difficulty and expense that many dealers would not be willing to undertake. We are concerned that sizeable numbers of small operations might leave the certification program and sell "bootleg" product locally, thus exacerbating the primary health concerns we are trying to address.

5. Is a performance standard of "nondetectable" really what is meant? For example, modern techniques such as polymerase chain reaction may be able to detect the presence of the DNA from *Vibrio vulnificus*, even though the organisms may be in a dormant and innocuous state. If this were so, no shellstock from implicated waters could be sold for raw consumption, whether processed or not.

Thank you for your consideration of these points.

Sincerely,

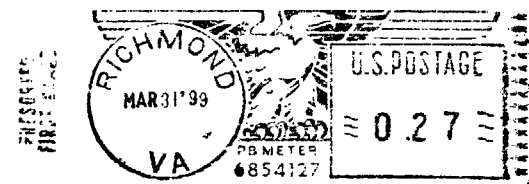
A handwritten signature in black ink, reading "Robert E. Croonenberghs". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Robert E. Croonenberghs, PhD, Director
Division of Shellfish Sanitation



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